

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

ICU MEDICAL, INC.,)	
)	
Plaintiff,)	C.A. No. 07-468-JJF
)	
v.)	JURY TRIAL DEMANDED
)	
RYMED TECHNOLOGIES, INC.,)	PUBLIC VERSION
)	
Defendant.)	

**ICU'S OPPOSITION TO RYMED'S MOTION IN LIMINE NO. 4 TO PRECLUDE
ICU FROM OFFERING EVIDENCE OF PRIOR ALLEGED COPYING
TO SUPPORT ALLEGATIONS OF COPYING IN THE INSTANT CASE**

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I. INTRODUCTION

RyMed Technologies, Inc.'s ("RyMed") motion to exclude evidence of RyMed's copying of other ICU Medical, Inc. ("ICU") products fails for at least two reasons. First, RyMed ignores the probative value of the evidence—it is highly relevant and admissible under at least Rule 404(b). Second, RyMed erroneously demands that ICU's expert, Mr. Claude Vidal, be precluded from opining about prior copying. But Mr. Vidal's opinion was not offered as scientific evidence or special knowledge in the manner that RyMed suggests, and it easily passes muster under Rule 702 in any event. RyMed's motion should be denied.

II. ARGUMENT

A. The Probative Value of Evidence Regarding Dana Ryan's Copying of ICU's Click Lock Device Substantially Outweighs Any Prejudice

RyMed's prior copying goes to at least two significant issues in the case: copying as a secondary consideration to obviousness and RyMed's intent to willfully infringe ICU's patents. *See, e.g., In re Brimonidine Patent Litig.*, 2009 U.S. Dist. LEXIS 103296, C. A. No. 07-md-1866 GMS, at *42–43 (D. Del. Oct. 23, 2009) (efforts by others to copy is one of the secondary considerations relevant to non-obviousness); *State Indus., Inc. v. A.O. Smith Corp.*, 751 F.2d 1226, 1236 (Fed. Cir. 1985) (knowledge of the patent is relevant to show willful infringement). That Mr. Ryan and his prior companies have followed ICU's products and patents closely, and routinely come out with similar ones, is directly tied to Mr. Ryan's awareness of and intent to copy ICU's patented CLAVE.

For nearly two decades, RyMed has been tracking ICU. In the 1980s, ICU launched a predecessor to the CLAVE, the Click Lock. The Click Lock was essentially a locking mechanism comprised of a protected needle, which served to prevent needle sticks. Years after the Click Lock came out, RyMed's CEO, Dana Ryan, filed a series of patents directed to a

similar protected needle locking mechanism and offered a product, apparently known as the Saf-T Klik. (*See, e.g.*, Declaration of Daniel Wan in Opposition to RyMed's Motions in Limine filed herewith ("Wan Opp. Decl."), Ex. 13 (U.S. Patent No. 5,139,483)). [REDACTED] [REDACTED], both during the prosecution of the '483 Patent, by citing to ICU's patent directed to the Click Lock device (U.S. Patent. No. 4,752,292); and during his most recent deposition. [REDACTED]

[REDACTED]

[REDACTED]

ICU then launched the CLAVE Needle-Free connector in March 1993. In December of that same year, Mr. Ryan also filed a patent application directed to a needleless valve. (*See* Wan Opp. Decl., Ex. 14 (U.S. Patent No. 5,395,348, entitled "Medical Intravenous Administration Line Connector").) Like the CLAVE, Mr. Ryan's '348 patent was directed to a "needleless" connector and claimed that it would offer "substantial advantages" in preventing accidental needle sticks. (*Id.*, Ex. 14 at 4:17-21.)

Two years later, Mr. Ryan filed another application, this time directed to a needle-free valve with even more features in common with ICU's CLAVE design. This application, which eventually issued as U.S. Patent No. 5,788,215 (entitled "Medical Intravenous Administration Line Connectors Having a Luer or Pressure Activated Valve"), includes features such as activation by a male luer and using a "luer lock connection." (*Id.*, Ex. 15 at 8:1-3, 8:4-6.) It also has seal aspects that appear similar to those claimed in ICU's patents. (*Id.*, Ex. 15 at 9:52-62.) And it claims to reduce "dead space" and to resist leaking after multiple activations. (*Id.*, Ex. 15 at 8:20-22, 8:32-35.)

In 1994, ICU introduced to the market its vial adapter. Within three years, Mr. Ryan filed an application that was also directed to a vial adapter. (*See* Wan Opp. Decl., Ex. 16 (U. S.

Patent No. 5,833,213 (entitled “Multiple Dose Vial Adapter for Use with a Vial Having a Pierceable Septum and a Needleless Syringe”).) Here again, some aspects of Mr. Ryan’s vial adapter bear an eerie resemblance to the features in ICU’s vial adapter patents and products. Compare ICU’s 6,599,273 Patent,¹ Figs. 33 and 34 (Wan Opp. Decl., Ex. 20) with ’213 Patent, Fig. 10.

It is no surprise that in 1997 (if not sooner), RyMed took its development process a step further and began to devise a copycat needle-free valve that, like ICU’s CLAVE, would be swabbable and luer-activated. It became known as the InVision-Plus, which is the accused product in this case. Mr. Ryan’s more recent patents and applications, also directed to the InVision-plus product, make it clear that he continues to monitor ICU’s patent portfolio. (See Wan Opp. Decl., Exs. 17–19 (U.S. Patent No. 6,113,068, entitled “Swabbable Needleless Injection Port System Having Low Reflux”; U.S. Patent No. 6,994,315, entitled “Swabbable Needle-Free Injection Port Valve System with Neutral Fluid Displacement”; and U.S. Patent App. No. 11/341,119, entitled “Swabbable Needle-Free Injection Port Valve System with Zero Fluid Displacement” (all citing ICU’s asserted 5,685,866 patent, among others, as prior art).)

ICU expects RyMed to present Mr. Ryan and his company as a team of innovators, with droves of patents and experience in this field. If RyMed takes this approach, then ICU should be allowed to rebut it with evidence that RyMed has, in fact, been following in ICU’s footsteps for nearly twenty years. This is particularly important given how closely the InVision-Plus resembles ICU’s patented CLAVE—it has even been referred to in the industry as the [REDACTED] [REDACTED] (See Wan Opp. Decl., Ex. 12.) RyMed should not be allowed to pretend that its

¹ The application that eventually issued as the ’273 patent was filed in 2000, but it is a continuation of (and therefore shares the same specification with) ICU’s abandoned application No. 08/265,095 filed on June 24, 1994.

design efforts on this copycat product started from a clean slate, when nearly *twenty years* of history proves to the contrary.

As explained above, RyMed's copying of a specific, prior product, the Saf-T Klik, which is the focus of RyMed's motion and apparently the only piece of evidence RyMed seeks to exclude, is but one example of Mr. Ryan's long history of shadowing and copying ICU. Nevertheless, the close resemblance of ICU's Click Lock and the Saf-T Klik is an important piece of this history, and ICU would be prejudiced if not allowed to raise it.

B. The Evidence of Prior Copying Is Admissible under Rule 404(b) for Purposes Other than to Show Conformity of Conduct

That RyMed quickly glides over numerous exceptions under Rule 404(b) is telling—evidence of Mr. Ryan's copying of the Click Lock falls squarely within several exceptions and is admissible. Fed. R. Evid. 404(b) (evidence of other wrong acts *is* "admissible for other purposes, such as proof of motive, opportunity, intent, preparation, plan, knowledge, identity, or absence of mistake or accident"). Rule 404(b) is a rule of "inclusion," rather than "exclusion," and admits evidence of other bad acts relevant to any issue in the trial, unless it only goes to show propensity to commit bad acts. *United States v. Givan*, 320 F.3d 452, 460 (3d Cir. 2003).

The similarities between Mr. Ryan's prior Saf-T Klik product and ICU's prior Click Lock product meet several exceptions. For example, this prior copying can go to knowledge and opportunity. Mr. Ryan [REDACTED]

[REDACTED]

[REDACTED]. The evidence is also relevant to intent or absence of mistake.

[REDACTED]

[REDACTED] that was no accident or coincidence. *Id.* Similarly with the CLAVE, [REDACTED]

[REDACTED]

[REDACTED]

RyMed also jumps the gun by presuming that ICU intends to use evidence of Mr. Ryan's prior copying as "[REDACTED]." (Mot. at 4.) While RyMed might feel that Mr. Ryan has done something untoward (and perhaps rightly so), ICU has not made any suggestion that the apparent similarity of other RyMed products with ICU's Click Lock is the result of any "[REDACTED]." ICU only seeks to demonstrate that Mr. Ryan's tracking of ICU's progress and product development, including repeatedly coming out with similar patents for decades, is a pattern of behavior relevant to this case. This is precisely the type of evidence contemplated by Fed. R. Evid. 404(b).² See, e.g., *Pennsylvania v. Porter*, 659 F.2d 306, 320 (3d Cir. 1981) (evidence of prior violations establishes a "pattern or practice" and was properly admitted); *United States v. Coleman*, 805 F.2d 474, 482 (3d Cir. 1986) (defendant's prior statements are probative of a "prior pattern" of dealing with the tax receipts and admissible); *United States v. Hill*, 629 F. Supp. 493, 495 (D. Del. 1986) (prior instances of bribery are admissible to show "common scheme or plan" under Rule 404(b)).

C. Mr. Vidal's Opinion Regarding Prior Copying Is Not Offered as Scientific Knowledge on Infringement and in any Event, Meets the Requirements of Rule 702

RyMed presumes that because Mr. Vidal opined on its copying of other ICU products, the opinion must be examined under Federal Rule of Evidence 702. RyMed is wrong. While Rule 702 governs the admissibility of expert testimony, Mr. Vidal's observation that the Saf-T Click is similar to ICU's Click Lock product is not intended to provide "scientific, technical, or other specialized knowledge" that "will assist the trier of fact to understand the evidence,"

² This type of evidence is also admissible under Fed. R. Evid. 406 as it is relevant to "the routine practice of [] an organization."

precisely because ICU's Click Lock and RyMed's Saf-T product are not at issue in this case.

Fed. R. Evid. 702. Mr. Vidal never opined that the Saf-T product was an exact copy for purposes of infringement or obviousness, and indeed, he didn't need to. Mr. Vidal simply observed that, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Thus, even if Rule 702 applies, Mr. Vidal's testimony meets it. Under the Federal Rules and *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993), the Third Circuit has construed Rule 702 as embodying "three distinct substantive restrictions on the admission of expert testimony: qualifications, reliability, and fit." *Elcock v. Kmart Corp.*, 233 F.3d 734, 741 (3d Cir. 2000). RyMed provides no evidence that Mr. Vidal is not qualified to compare two products—indeed, as a designer of medical valves for thirty-four years, he is amply qualified. Nor has RyMed shown that Mr. Vidal's opinion on this point is unreliable. Mr. Vidal's opinion is that, based on just a cursory examination, [REDACTED]. It is not intended to be an exact comparison; and it is not intended to be an infringement analysis. It is merely the observation of one skilled in the art that [REDACTED]

[REDACTED]. As stated in the previous paragraphs, this evidence is relevant to a host of issues, including knowledge, intent, and lack of mistake.

III. CONCLUSION

Mr. Ryan has been shadowing ICU for years. Now that he has outwardly created a true copy of one of ICU's flagship products, it would be extremely prejudicial to preclude ICU from informing the jury of this long history with ICU. RyMed offers no legitimate basis to exclude

testimony or evidence comparing ICU's Click Lock to RyMed's Saf-T Clik product, which is a significant part of this history, and RyMed's motion should be denied.

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CERTIFICATE OF SERVICE

I, David E. Moore, hereby certify that on December 11, 2009, the attached document was electronically filed with the Clerk of the Court using CM/ECF which will send notification to the registered attorney(s) of record that the document has been filed and is available for viewing and downloading.

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